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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,062	12/08/2005	Alan Cuthbertson	PN0353	8021

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GE HEALTHCARE, INC.
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,062	CUTHBERTSON ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the of the amendment filed 12/8/05 wherein the specification was amended and claims 5-13 were amended.

Note: Claims 1-13 are pending.

APPLICANT'S INVENTION

2. The claims are directed to a compound comprising at least one fluorescein dye in combination with the amino acid sequence X3-G-D wherein X3 is arginine, N-methylarginine, or an arginine mimetic.

DOUBLE PATENTING REJECTIONS

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-8 and 10-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 23-26, 28, and 29 of copending Application No. 12/053,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to X3-G-D containing species and uses thereof wherein X3 is arginine, N-methylarginine, or an arginine mimetic. The claims differ in that those of 10/560,062 are not limited to compounds containing two cyclizing bridges. Thus, the skilled artisan would recognize that claim 1 in the instant invention encompasses the invention of 12/053,829. In addition, claim 23 of 12/053,829 disclose that the vector is conjugated to an imaging moiety. A skilled artisan would recognize that fluorescein is an imagable moiety. Hence, the claims disclose overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-12, 19, 23-27, and 30 of copending Application No. 11/570,090. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a compound comprising X3-G-D compounds and uses thereof wherein X3 is arginine, N-methylarginine, or an arginine mimetic. In addition, claim 19 of 11/570,090 disclose that a fluorescent dye may be attached to the compound. The claims differ in that those of the instant invention are not limited to X3G-D containing species wherein the compound contains two cyclized bridges..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-8 and 10-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13, and 14 of copending Application No. 11/813,445. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compounds and uses thereof comprising and X3-G-D compound attached to an optical imaging reporter. The claims differ in that those of the instant invention are directed to a fluorescein reporter. Thus, the skilled artisan would recognize that the instant invention is encompassed by the invention of 11/813,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-10 of copending Application No. 12/141,123. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to R-G-D containing species that is attached to a reporter moiety. The claims differ in that those of the instant invention specifically disclose that the reporter moiety is fluorescein. Thus, the skilled artisan would recognize that the instant invention is encompassed by the invention of 2/141,123 because the R-G-D compound of the instant invention is not limited to species containing two cyclized bridges as set forth in 12/141,123.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 SECOND PARAGRAPH REJECTIONS

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13: The claims as written are ambiguous because one cannot ascertain what species are encompassed by the terms 'arginine mimetic'. Review of the specification does not set forth a definition of how Applicant is interpreting the

phrase. The phrase appears in independent claim 1, line 5. Thus, since claims 2-13 depend on claim 1, those claims are ambiguous as well.

Claim 2, line 9: The claim as written are ambiguous because of the phrase 'possesses a functional side chain such as and acid or amine group. In particular, regarding claim 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 2 and 5, lines 12 and 4, respectfully: The claim as written is ambiguous because of the term 'derivatives'. In particular, it is unclear what portion of the parent structure remains in the derivative. Thus, one cannot ascertain what is being claimed.

Claim 2, line 14: The claim as written is ambiguous because of the phrase 'biomodifier moiety'. In particular, review of the specification does not set forth a definition for bimodifier moiety. Thus, one cannot ascertain what is being claimed.

Claim 5, line 2: The claim as written are ambiguous because of the phrase 'possesses a functional side chain such as and acid or amine group. In particular, regarding claim 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 11 provides for the use of the compound as an optical imaging contrast agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is

indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12: The claim as written are ambiguous because it is unclear what the actual active steps are in the claim. In addition, it is unclear what is being claimed. Specifically, is Applicant claiming a method of diagnosing some condition, a method of imaging, etc.? Please clarify the claim in order that one may ascertain what is being claimed.

Claim 13: The claim as written is ambiguous because of the awkward claim language. In particular, the phrase 'contrast agent has distributed...claim 1' is confusing.

101 REJECTIONS

10. Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

102 REJECTION

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Klaveness et al (US Patent No. 6,331,289).

Klaveness et al disclose targetable diagnostic and/or therapeutically active agents. In particular, the composition comprises a RGD peptide and fluorescein. The peptide-fluorescein composition may be in the form of microbubbles (columns 74-75, Example 13). Thus, both Applicant and Klaveness et al disclose overlapping subject matter.

PRIORITY DOCUMENT

13. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

COMMENTS/NOTES

14. Applicant's is respectfully requested to submit a copy of the lined through document listed on the information disclosure statement.

15. Applicant is respectfully requested to correct the claim dependency of claim 3. In particular, claim 3 is an improper multiple dependent claim. Applicant is respectfully requested to review MPEP 608.01 for proper claim format.

16. Applicant is reminded that it has been held that the recitation that an element is 'capable of' performing a function is not a positive limitation, but only requires the ability to so perform that function. Thus, such terminology does not constitute a limitation in any patentable sense (In re Hutchison, 69 USPQ 138).

Note: Claims 2 and 3 contain 'capable of' terminology.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

December 20, 2008